Instructions for Use

US Patents 6,059,795; 6,074,399
and other patents pending

CLINICAL
INNOVATIONS

IT'S ALWAYS MORE POSTERIOR THAN YOU THINK

excerpt from

A poem by Aldo Vacca

Vacuum extraction may drive some to distraction
While others may find comfort in a drink
Though life's replete with cliches, the answer is in the catch phrase:
"It's always more posterior than you think"

There is clinical confusion at the vacuum cups' profusion
Made of plastic, rubber, steel or alloyed zinc
But design, not the make-up is the feature that will make cups
Move a little more posterior than you think

Need and good intention are the mother of invention
New cups appear as quick as you can blink
When the head is mal-rotated, the flexion point is situated
A good deal more posterior than you think

To find the point that's flexing should never be perplexing
It's on the vertex, in the midline not the brink
Three centimeters or an inch plus, from the landmark well used by us
And often more posterior than you think

Some cups I've heard it muttered, look like metal "cookie cutters"
Or a tool that's used to clear the kitchen sink
In jest it's called a "Hoover" but the trick is to maneuver cups
To place them more posterior than you think

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Kiwi System

Device Description

The Kiwi vacuum delivery device is an integral unit designed for complete control without an assistant. The PalmPump provides safe and effective vacuum control.

The Kiwi system has been designed with two different style cups: The ProCup for outlet and low occiput anterior positions and the OmniCup for all positions including asynclitic occiput posterior and lateral fetal malpositions.

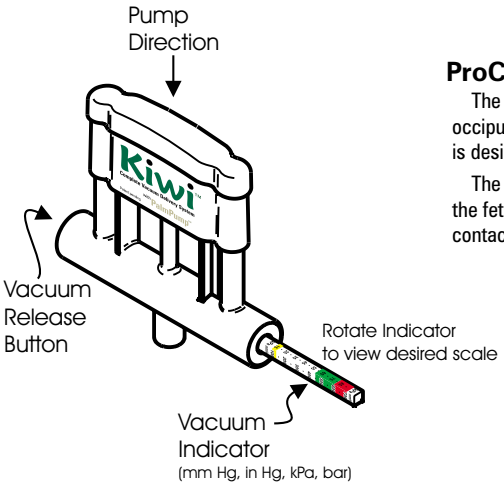
These instructions are not meant to replace established hospital protocol.

Palm Pump™

The PalmPump puts complete control in the hands of a single operator and frees up delivery room personnel.

The PalmPump's integral design provides:

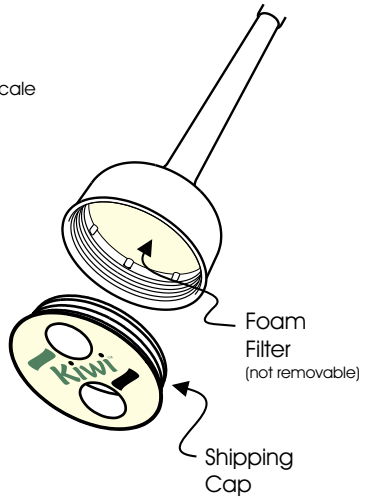
- A simple hand vacuum pump,
- Thumb or finger activated vacuum release valve, and
- Accurate vacuum indicator.



ProCup™

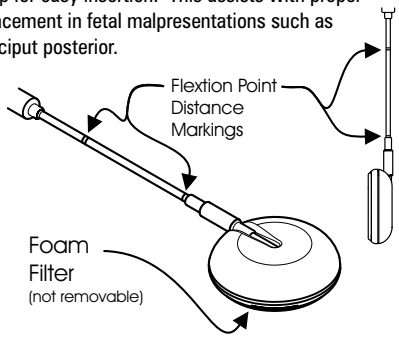
The Kiwi ProCup is for use with low occiput anterior, and outlet presentations and is designed to reduce chignon.

The soft flexible cup expands and molds to the fetal head which safely increases cup contact area and vacuum hold.



OmniCup™

The Kiwi OmniCup (a universal cup for all presentations) has a low profile with a handle grip for easy insertion. This assists with proper placement in fetal malpresentations such as occiput posterior.



Candidate Selection

Steps in Selection of Patients*

Patients suitable for vacuum extraction may be selected by reviewing history of pregnancy and labor, assessing condition of fetus and mother, and evaluating abdominal and vaginal findings.
Selection procedure should include these steps:

Review History of Pregnancy and Labor

- Check for high risk obstetric and general medical factors.
- Assess frequency and strength of uterine contractions.
- Note any contraindications to use of oxytocin infusion.

Assess Maternal Condition

- Evaluate physical and emotional state of mother and her ability to participate actively in birth.
- Reduce discomfort by administering appropriate analgesi.
- Relieve apprehension by explaining reasons for procedure.
- Check maternal blood pressure, temperature, pulse rate and fluid balance.
- If urine output is low, a catheter should be inserted into bladder to determine whether cause of reduced output is dehydration or urethral compression by fetal head.

Assess Fetal Welfare

- Note color of liquor for presence of meconium or blood.
- Assess fetal heart rate pattern by auscultation or continuous electronic monitoring.
- If fetal jeopardy is suspected, scalp blood sampling for pH estimation may help establish correct diagnosis.

Abdominal Examination

- Catagorize size of baby into small, average or large.
- Assess number of fifths of head palpable.
- Identify position of fetal back and sinciput.
- Look for distension of lower uterine segment or formation of a retraction ring indicating that labor may have become obstructed.

Vaginal Examination

- Estimate dilatation of cervix and station of presenting part.
- Grade degree of molding as slight, moderate or severe.
- Diagnose position of head and extent of deflexion and asynclitism.
- Locate flexion point.

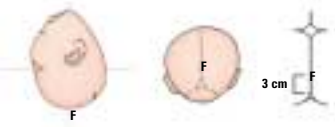
Table 1 **Selection of patients**

Station	Level	Fetal distress	Molding	Method of delivery
Outlet	0/5	Yes or no	Slight to severe	Vacuum extraction (VEx)
Low (Pelvic floor)	0/5	Yes or no	Slight to severe	VEx (occ. malposition)
Mid pelvis	1/5	No	Moderate	VEx (freq. malposition)
Mid pelvis	1/5	Yes	Moderate	Trial of VEx (or C/S)
Mid pelvis	1/5	No	Severe	Trial of VEx (or C/S)
Mid pelvis	1/5	Yes	Severe	Caesarean section (C/S)
Upper pelvis	2/5	Yes or no	Slight to severe	Caesarean section (C/S)

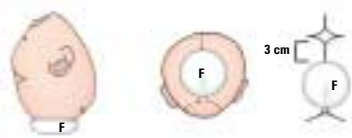
From: Vacca A. Handbook of Vacuum Extraction

* Refer to Indications for Use and Contraindications located on package label.

Flexion Point



The flexion point is situated on the sagittal suture 3 cm forward of the posterior fontanelle.



Flexing Median Application

The center of the vacuum cup should be placed over the flexion point with the sagittal suture in the midline.

Labor Process Enhancement

- Correct technique should enhance the normal processes of labor and should not depend on traction alone to effect delivery of the baby.
- The key is to locate the flexion point and place the vacuum cup properly over it.
- The flexion point is situated on the sagittal suture 3 cm in front of the posterior fontanelle.

Diameters of Fetal Head

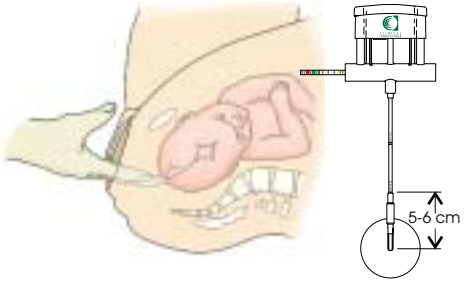
- When a vacuum cup is attached to the head and traction is applied, the cup becomes the leading part.
- The center of the cup should correspond to the flexion point so that traction in the line of the pelvic axis will promote flexion and synclitism.
- This will result in the most favorable presenting diameters of the head leading through the birth canal.

Flexion Point Location

The flexion point may be located during vaginal examination by identifying the posterior fontanelle and then moving the finger anteriorly a distance of approximately 3 cm along the sagittal suture. The tip of the finger will mark the flexion point.

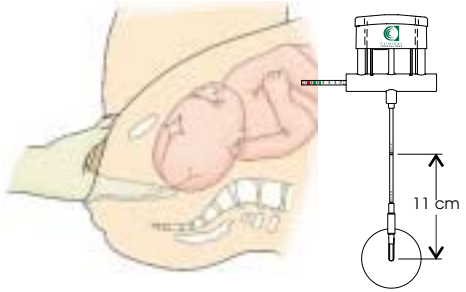
Two observations are required:

- Distance from flexion point to posterior fourchette.
- Degree of lateral displacement of the flexion point from the midline axis of the pelvis.



Distance Measurement

- Place tip of examining finger on flexion point
- Calculate distance from flexion point to fourchette by measuring distance from tip to where finger makes contact with fourchette.
- The distance from the tip of the middle finger to the proximal interphalangeal joint is 5 - 6 cm, and to the metacarpophalangeal joint is 10 - 11 cm.
- OmniCup tubing has markings to assist the user in the location of these distances as shown in the figures. These markings also help to identify how much progress is made during each contraction.



Lateral Displacement

- Place tip of index finger of left hand under symphysis pubis to mark midline reference position.
- Identify flexion point as previously described.
- Observe distance between finger tips to estimate extent of lateral displacement or rotation of flexion point.

3.

Cup Type Selection

ProCup (occipitoanterior presentations)

The Kiwi ProCup is suitable for occipitoanterior positions where the flexion point is near the introitus. Maneuverability of the ProCup cup is limited by the cup stem pressing against the labial tissues and perineum.

The ProCup cup is maneuvered by pushing the cup in the direction of the flexion point until further movement is inhibited as seen below.

The ProCup is not suitable for use in the majority of midcavity occipitoposterior or deflexed occipitolateral positions because the flexion point in these cases is usually located outside the range of movement of the cup, thus making it difficult or impossible to achieve a correct (flexing median) application.

The Kiwi ProCup is for outlet and low occiput anterior presentations. A good rule of thumb is to not use the ProCup unless you can see the fetal head between contractions.

OmniCup (occipitoposterior/lateral presentations)

The OmniCup is not restricted by the soft tissues of the vulva and perineum in its movements because the suction tube is in the same plane as the body of the cup.

This feature allows the cup to be easily inserted through the introitus, maneuvered under the caput and can be directed towards and over the flexion point.

Movement of the OmniCup in the birth canal is limited only by the amount of space between the fetal head and mother's sacrum posteriorly and the side walls of the pelvis laterally.

Provided the operator is skilled in the use of this cup, flexing median applications may be achieved consistently in nearly all malpositions of the occiput.

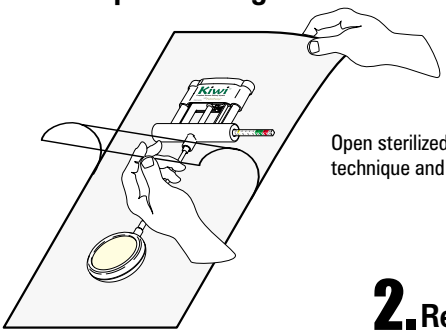
Thus, the OmniCup should, by permitting better applications, decrease failure rate when the occiput is lateral or obliquely posterior. The OmniCup can also be used in outlet and low occiput anterior presentations.

Device Preparation

Informing the Parents

If a decision is made to expedite the birth of the baby and circumstances are suitable for vacuum extraction, the obstetrician should spend a short time explaining to the parents the reasons for the decision and the options available for subsequent management.

1. Open Package

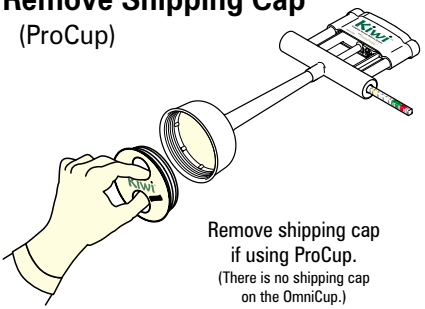


Open sterilized package using aseptic technique and remove Kiwi from package.

Note: The Kiwi system helps avoid waste. Since the Kiwi is an integral unit and no setup is required, the package does not need to be opened until immediately before use.

2. Remove Shipping Cap

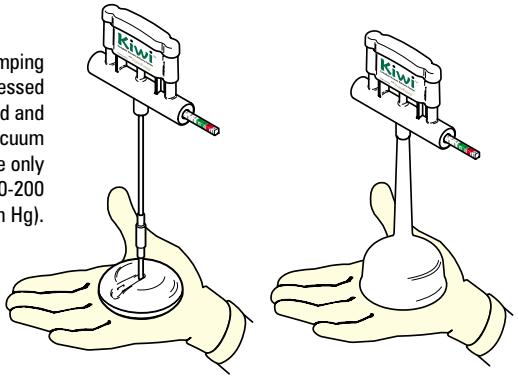
(ProCup)



Remove shipping cap if using ProCup.
(There is no shipping cap on the OmniCup.)

3. Check Vacuum

Check vacuum by pumping with cup pressed to gloved hand and watching for stable vacuum indicator reading. (One only needs test to 100-200 mm Hg).



Note: Due to the softness and elasticity of the ProCup, the cup may collapse on itself when applied to a flat surface (such as the palm of the hand) when vacuum exceeds 200 mm Hg. This does not occur when applied to the fetal head as the cup forms to the shape of the head. Fluid may be drawn into the pump, but it will not affect pump function.

Cup Insertion

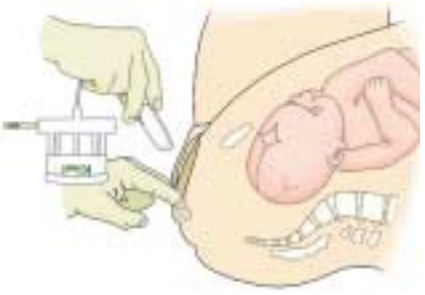
Positioning of the Mother

The lithotomy position with a wedge under one maternal buttock to produce some lateral tilt is recommended for vacuum extraction. In this position, orientation and location of the flexion point and correct application of the cup is most readily achieved.

When the mother has been assisted into the lithotomy position, the buttocks should extend as far as, or slightly beyond, the end of the bed to allow traction to be directed downward towards the floor if necessary.

Cup Insertion

- Perform vaginal exam to ensure amniotic membranes are ruptured, cervix is completely dilated and effaced and to determine fetal presentation, position, and flexion point location.
- Retract perineum with two fingers of non-pulling hand to form a space into which cup is inserted gently in one movement.
- If using ProCup, slightly rotate to ensure cup edges unfold.
- Press cup against fetal head and manoeuver until its center lies over flexion point.
- Check that cup is correctly placed by noting that there is a distance of at least 3cm between anterior fontanelle and nearest part of cup (application distance) and that sagittal suture passes under middle of cup.
- Check that there is no maternal tissue or a fetal electrode trapped between cup and scalp in anterior positions, by holding cup in position with one hand and running index finger of other hand around rim of cup (With occipitolateral and posterior positions, it is usually impossible to reach behind a correctly placed cup without displacing the cup.).
- Initiate cup seal by raising vacuum to approximately 100 mm Hg (yellow zone) on Palm Pump vacuum indicator.
- Re-examine to ensure no maternal tissue has been drawn under cup and reapply cup if necessary.



Posterior & lateral Presentations, etc...

OA - Outlet Presentations Only

DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR.
ONLY PLACE CUP OVER FLEXION POINT.

Vaginal Delivery

Positioning of the Operator

The operator should sit on a stool until the head has descended to the level of the pelvic outlet so that traction will be exerted in a downward direction and assist descent of presenting part by maintaining the flexion point on or just behind axis of pelvis.

The operator should change the direction of traction progressively upwards for low extractions or as the fetal head descends to the outlet. As this is done, the standing position becomes more appropriate.

For rotational extractions from the midpelvis, the operator may find it easier to direct traction towards the floor by getting down on one knee for the initial pull.

Eye contact should be maintained between the mother and operator at all times so that communication and interaction can occur freely.

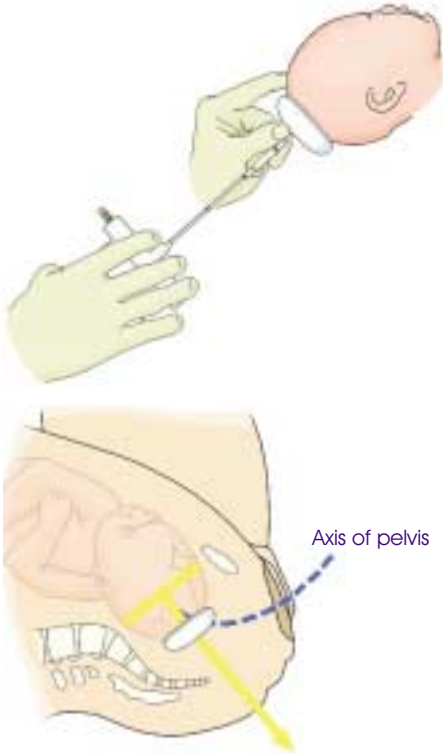
Traction

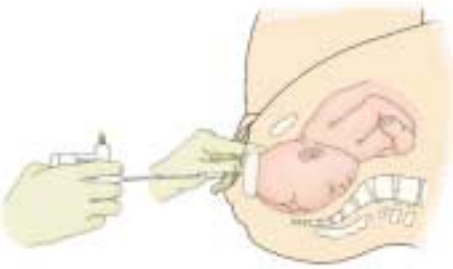
- Once contraction begins, rapidly raise vacuum to 450-600 mm Hg (green zone) according to hospital protocol.
  DO NOT EXCEED 620 mm Hg (RED ZONE)
- Press against dome of cup with thumb of non-pulling hand and feel cup edge to help prevent cup detachment from scalp and detect early signs of detachment. Reduce traction force accordingly.
- Rest index finger of same hand on scalp in front of cup and monitor descent of head.
- Apply traction in line with pelvic axis and draw fetal head down over perineum with each contraction.
- For maximum efficiency and best results, direct pull perpendicular to cup. However, with midpelvic rotational procedures, oblique traction is often necessary and caution must be exercised because oblique tractional forces may increase predisposition to cup detachments.
- Exercise caution. Pendulum or rocking movements from side to side may also increase predisposition to cup detachment.
- Maintain constant traction for duration of contraction.
- Discontinue traction between contractions or if an audible hiss is heard, signaling loss of vacuum.
- Reduce vacuum (yellow zone) between contractions (optional) per hospital protocol.
- Repeat steps until delivery of head is complete or until maximum recommended time or re-application limits are met.

Table 2 Equivalent negative gauge pressures

Kg/cm²	kPa	mm Hg	Inches Hg	cm H_2O	lb/in²	bar
0.13	13	100	3.9	134	1.9	0.13
0.27	27	200	7.9	268	3.9	0.26
0.41	40	300	11.8	402	5.8	0.39
0.54	53	400	15.7	536	7.7	0.53
0.68	67	500	19.7	670	9.7	0.66
0.82	80	600	23.6	804	11.6	0.79
0.95	93	700	27.0	938	13.5	0.92
1.03	101	760	29.9	1018	14.7	1.00

From: Vacca A. Handbook of Vacuum Extraction.





Progress

The first pull should cause flexion of the head and some descent. By the end of the second pull the head should be on the pelvic floor and with the third pull, delivery of the head should be complete or imminent.

With strong contractions and effective maternal expulsive effort, delivery should be achieved as follows:

- 1 or 2 pulls for outlet vacuum extractions,
- 2 or 3 pulls for low vacuum extractions,
- 3 or 4 pulls for mid pelvic procedures.

Note: If traction is misdirected or too forceful, vacuum may be broken. Before replacing cup, examine fetal scalp for trauma and re-assess presentation and position.

DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.

DO NOT REAPPLY IF CUP HAS BEEN DISENGAGED TWO TIMES

Delivery

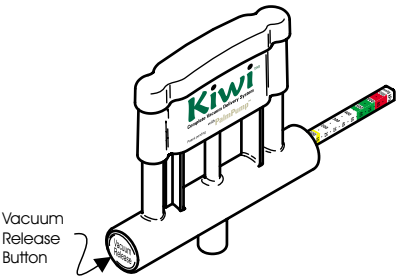
- Release vacuum with release button after delivery of head.
- Ease cup off the scalp.
- Complete birth in normal manner.

After Delivery

- Examine baby's head immediately after birth for scalp injury and note cup application site.
- Inspect scalp regularly if difficulty was experienced to exclude bleeding into the subgaleal space.
- Reassure parents that chignon should disappear in a matter of hours and that marks from cup should leave no traces after a few days.
- Reexamine baby within 24 hours to check the application site of vacuum cup.

Disposal

- Discard disposable cup and PalmPump using appropriate procedure.



Cesarean Delivery

Preparation

- Follow device preparation steps.
- Dissect uterus using normal procedure and assess fetal head position.

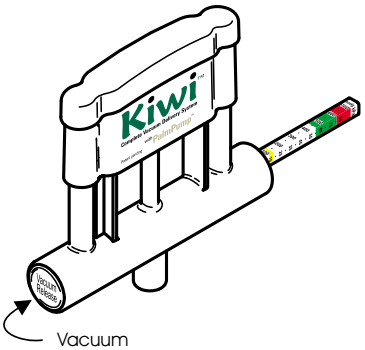
Cup Insertion

Insert cup and:

- If head is high, place cup over occiput.
- If head is low, gently flex upward into uterine incision with fingers and place cup over occiput.
  DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR
- Check edges of cup to ensure no maternal tissue has been drawn under cup.
- Raise vacuum to 100 mm Hg (yellow zone) and recheck cup edges

Delivery

- Raise vacuum to 450-600 mm Hg (green zone)
- Gently draw fetal head upward through incision
- When fetal head is delivered, release vacuum with release valve and remove cup before continuing normal delivery of shoulders and body.



Reorder Information

Part No.	Description	Qty/Box
VAC-6000S	**ProCup™** (soft bell shaped cup)	5
VAC-6000M	**OmniCup™** (Malmstrom-style cup)	5

P/N 050-0142 Rev. B

CLINICAL INNOVATIONS

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